REMARKS

Claims 3 and 5-9 are pending. Claims 4 and 5 have been withdrawn from consideration.

In the Office Action mailed March 26, 2008, claims 3 and 5-9 have been rejected as allegedly anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 5,698,195 to Le et al. ("*Le*"). Claims 3 and 5-9 have also been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

By this Amendment, Applicant amended claim 3. Applicant respectfully request reconsideration and allowance of the pending claims in view of the amendments and remarks set forth below.

I. AMENDED CLAIM 3 IS SUPPORTED IN THE APPLICATION AS FILED

As amended, claim 3 now recites:

> 3. (Currently Amended) A medicament effective in correcting pathologic immune reaction, ~~the~~ said medicament comprising a homeophathically activated ~~one or more homeopathic dilutions of potentiated~~ form of at least one monoclonal ~~or~~ polyclonal or natural antibody ~~antibodies~~ to a recombinant human or heterologous tumor necrosis factor alpha (TNA-α)~~, wherein one or more of the homeopathic dilutions of the potentiated antibodies to TNF-α, being obtained by a homeopathic potentiation technology~~.

Applicants are fully aware that the newly added limitation "homeopathically activated" is not set forth in the application in *ipsis verbis*. For this reason and to advance the prosecution on the merits, Applicants wish to address the issue preemptively and directly for Examiner's consideration.

Applicants note that *haec verbis* disclosure is not a pre-requisite for complying with the written description requirement. *See* MPEP § 2163. I. B. The description may be express, implicit, or inherent. *Id.* The key to evaluating compliance with the written description requirement is a determination whether the applicant had possession of the claimed invention based on the content of the application as a whole. *See* MPEP § 2163. II. The outcome of the evaluation depends on whether "the description clearly allows

persons of ordinary skill in the art to recognize that he or she invented what is claimed." *See* MPEP § 2163.01, *citing In re Gostelli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

The specification describes: a) preparation of "activated" or "potentiated" antibodies to TNF-α by homeopathic technology (*e.g.*, at page 2, 3rd and 4th paragraph), b) administration of the activated or potentiated form of the antibody to TNF-α to patients (*e.g.*, Examples 3 and 4), and c) biological effects of such administration in an animal model (*e.g.*, Examples 1 and 2).

The terms "potentised" or "activated," as well as C30 or C100 with respect to dilutions, has a well defined meaning in the homeopathic art. Attached herewith as an Exhibit is an excerpt from a published English language translation of German Homoeopathic Pharmacopoeia (GHP) (1991). GHP is a voluminous, standard reference text on homeopathy. The attached Exhibit includes the i) the title page, ii) the content page, iii) a page from the section entitled "Formulations and Presentations," and iv) a portion of the monograph entitled "Manufacture." In the section of the attached Exhibit II entitled Formulations and Presentations, the GHP teaches:

> Liquid formulations are mother tinctures and solutions, as well as liquid dilutions of these; solid formulations are triturations of these (triturations). Different concentrations of these formulations (degrees of dilution) are obtained by *potentization*.
>
> *Potentization* in this context is the dilution by stages of solid or liquid formulations by the stated Method.
>
> The letter x [D in German usage] is used to designate dilutions made in a ratio of 1:10, the letter c [C in German usage] dilutions made in a ratio of 1:100.
>
> A figure added to the designatory letters 'x' and 'c' refers to the number of dilution stages [*emphasis in the original*].

In the section entitled "Manufacture," the GHP describes standard homeopathic preparation technologies for various known homeopathic preparations. For each described method, the GHP describes the necessary potentization methodology. It is clear that the meaning of the term "homeopathic activation or potentization" was well defined to one skilled in the art at the time of filing of the '651 application. In

combination, these disclosures clearly place "homeopathically activated form" of the antibodies in possession of the inventors as of the filing date of the '651 application.

Therefore, Applicants respectfully submit that amended claim 3 is fully supported in the application as filed.

II. ANTICIPATION REJECTION OVER *LE*

Claims 3 and 5-9 have been rejected as anticipated by *Le*. *Le* teaches antibodies to TNF-α at standard concentrations. The Examiner stated that the term "potentiated antibodies" and 'homeopathic potentiation technology" is not defined and thus the claimed form of antibodies encompasses the antibodies of *Le*. Claim 3 had been amended to clarify the scope of the claimed subject matter.

To anticipate a claim, a reference must disclose either explicitly or inherently, each element of the claim "as set forth in the claim." MPEP §2131, *citing*, *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Inherent anticipation requires a showing that, while not disclosed explicitly, the prior art composition is identical in fact and possess the properties of the claimed invention. MPEP §2112. Further, to establish a *prima facie* case of inherent anticipation, the Examiner must show scientific rationale or objective evidence tending to show inherency. *See* id. The evidence in the file wrapper is directly to the contrary: *Le* teaches antibodies at standard concentrations.

It is apparent that *Le* does not anticipate the amended claim 3. Nothing in *Le* teaches anything related to homeopathy, let alone to "homeopathically activated form of antibodies." Withdrawal of the anticipation rejection is respectfully requested.

Furthermore, *Le* cannot render a "homeopathically activated form of antibodies" obvious. The Examiner is respectfully requested to closely consider the differences between the antibodies claimed in the present invention and the standard antibody preparations. The issue with respect to obviousness under the current law is whether the prior art in its entirety provides "an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co. v. Teleflex Inc., 127 S. Ct.*

1727, 1742 (2007). Nothing in the prior art of record suggests the claimed form of antibodies.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-4711

Respectfully submitted,

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